

Remarks

Claims 1-2, 4-8, 10, 12-20, 22-26, 28-30, 33-37, and 39-41, 43-66 are presented for the Examiner's review and consideration. Applicant believes the accompanying remarks serve to clarify the present invention, and are independent of patentability. No new matter has been added.

35 U.S.C. §102(b)

Claims 13-18, and 39, were rejected under 35 U.S.C. §102(b) as being anticipated by Jenkins, Jr. (U.S. 5,722,978, "Jenkins"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Jenkins

Jenkins discloses an osteotomy guide and surgical kit for performing a tibial osteotomy. (Abstract). "The osteotomy guide comprises two or more rows of guide holes formed therethrough for attaching the guide onto a pair of guide pins in a predetermined relation to a tibia; a transverse slot, defining a transverse cutting plane, adapted to receive and guide a transverse cutting blade for making a transverse cut into the tibia; and a plurality of oblique slots angularly offset from the transverse slot, each oblique slot defining an oblique cutting plane, adapted to receive and guide an oblique cutting blade for making a selected oblique cut into the tibia, wherein the intersection of each of the oblique cutting planes with the transverse cutting plane is adapted to define a wedge of bone which may be removed from the tibia." (C3L47-61).

Jenkins does not disclose a total knee replacement cutting guide, as recited in claim 13, but rather, only a guide for a tibia, in order to correct an alignment thereof. In particular, there is no disclosure within Jenkins of replacing any portion of either the tibial or the femoral articulating surfaces, which are requirements of a total knee replacement. Jenkins is merely removing a wedge of bone in an operation "performed very close to the knee joint" (C2L47-48), and not on the knee joint itself. As such, at least for this reason, Jenkins cannot anticipate all of the claim elements of claim 13.

Moreover, the guide of Jenkins is not "custom fabricated for a single patient's bone", as recited in claim 13, but is fabricated the same way for all patients, the guide including the same

series of slots for every patient. The medical practitioner merely selects among predefined slots for a particular patient. Thus, the aforementioned claim element is additionally missing in Jenkins.

Accordingly, Applicant respectfully submits that claim 13 is patentable over Jenkins. As claims 14-18, 34, and 39, depend from claim 13, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Jenkins for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the §102(b) rejection.

35 U.S.C. §102(e)

Claims 13-18, and 39, were rejected under 35 U.S.C. §102(e) as being anticipated by Mansmann (U.S. 6,132,468, “Mansmann”). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Mansmann

In Mansmann, a flexible "scaffold" envelope is disclosed which can be used to replace damaged cartilage in knees, shoulders, or other joints of a mammalian body. (Abstract). “Designed for use in arthroscopic surgery, the envelope is sufficiently flexible to allow it to be rolled up or folded and inserted into a knee or other joint via a small skin incision. Before insertion, a segment of damaged cartilage is removed from a bone surface, and the bone surface is prepared...” (Id). “After anchoring, the envelope is filled via an inlet tube with a polymeric substance that will set and solidify at body temperature.” (Id).

“Travelling guide 202 is shown in a simplified manner, with orifice 230 passing through it to hold a burr shaft or other tool.” (C18L31-33). “This type of travelling guide can be used to establish **a reproducible arc** which is aligned in a way that can be used to prepare a femoral condyle for implantation of a scaffold envelope. If the lengths of **all four struts are identical**, and if the vertical spacing between the travelling pins 222 is identical to the vertical spacing of the fixed pins 220, travelling guide 202 will pass through a simple circular arc, having a radius equal to the lengths of the struts.” (C18L37-44).

“Alternately or additionally, computerized control systems can also be used, in which a computer is programmed to operate a device that moves a rotating burr, laser, or other tool through a complex two- or three-dimensional pathway.” (C19L33-36).

Thus, Mansmann does not suggest or teach a guide that is “custom fabricated for a single patient’s bone”, as recited in claim 13, but rather, discloses a guide that is fabricated the same way for all patients, the guide including the same series of slots, cams, or struts for all patients. The medical practitioner merely selects among cams or mounting points for the struts; the guide, having already been fabricated in a generic way, is now simply used as fabricated. Thus, the aforementioned claim element is missing in Mansmann.

Alternatively, Mansmann suggests one skilled in the art may use a “computerized control system” and “a complex two- or three- dimensional pathway” to guide bone preparation, but does not teach or disclose a specific system. Certainly, no such system is suggested or disclosed where a cutting guide is “custom fabricated for a single patient’s bone”.

Most particularly, in contrast to claim 13 of the instant invention, Mansmann discloses *an implant* that is customized for a single patient, and *not a guide*, as is claimed. As stated in Mansmann, after being cemented and anchored “the scaffold is then filled with the remaining desired quantity of polymeric liquid, to expand and enlarge the scaffold to its final desired thickness. While the injected polymer is setting and gradually hardening, the outer articulating surface of the scaffold can be manipulated and shaped in various ways, so it will have the desired final shape and contours after the polymer inside the scaffold fully sets and hardens.” (C21L56-64).

Accordingly, Applicant respectfully submits that claim 13 is patentable over Mansmann. As claims 14-18, 34, and 39, depend from claim 13, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Mansmann for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the §102(e) rejection.

Allowable Subject Matter

Applicant acknowledges with appreciation that claims 1-2, 4-8, 10-12, 19-20, 22-26, 28-30, 33-37, 40-41, and 43-66 were allowed.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

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